REMARKS

This communication is being filed in response to the Office Action dated October 8, 2003. Claims 1-3 are pending. Claims 1-3 are rejected under the judicially-created doctrine of obviousness-type double patenting. Claims 1-3 are rejected under the second paragraph of 35 U.S.C. § 112 as being indefinite. Claims 1-3 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bot *et al.* (*Viral Immunology* 1996;9(4):207-210), Lai *et al.* (*Hepatology* 1993;18:763-767), Assateerawatt *et al.* (*Asian Pacific Journal of Allergy and Immunology* 1993;11:85-91), and/or del Canho *et al.* (*J. Medical Virol.* 1993;41:30-34).

Applicants amend Claims 1-3 as indicated hereinabove. Applicants assert that these amendments do not constitute the introduction of new matter.

Applicants respectfully traverse the Examiner's rejections of the aforementioned claims for the reasons set forth below.

I. The Specification Complies with the Requirements of 37 C.F.R. §§ 1.821-1.825

The Examiner notes that the instant application contains sequence disclosures that do not comply with the requirements of 37 C.F.R. §§ 1.821 through 1.825. In response, Applicants submit herein paper and computer-readable copies of a Sequence Listing for the above-captioned application. Applicants hereby state that the content of the paper and computer readable copies of the Sequence Listing submitted in accordance with 37 C.F.R. § 1.821(c) and (e), respectively, are the same. Applicants hereby state that the content of the paper and computer readable copies of the Sequence Listing, submitted herewith in accordance with 37 C.F.R. § 1.82(f), does not include new matter.

II. The Rejection of Claims 1-3 are Obviated by the Filing of a Terminal Disclaimer

Claims 1-3 are rejected under the judicially-created doctrine of obviousness-type double patenting. According to the Examiner, Claims 1-3, while not identical to Claims 1-19 of U.S. Patent No. 6,204,250, are not patentably distinct from these latter claims because Claims 1-3 of the instant application and Claims 1-19 of U.S. Patent No. 6,204,250 are both drawn to a method of immunizing an infant against a target antigen, wherein the antigen is a viral antigen. The Examiner asserts that Claims 1-3 of the instant application would be anticipated by the patented claims.

To further the prosecution of the instant application, Applicants herewith file a Terminal Disclaimer pursuant to 37 CFR § 1.321(c) and compliant with 37 CFR § 3.73(b). Applicants note that the filing of this disclaimer is not an admission of the propriety of the Examiner's rejection of these claims. *See Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 20 USPQ2d 1392. In light of this disclaimer, Applicants respectfully request that the rejection of Claims 1-3 under the judicially-created doctrine of obviousness-type double patenting be withdrawn and that Claims 1-3 be allowed to issue.

III. The Claims are Definite

Claims 1-3 are rejected under the second paragraph of 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Specifically, the Examiner asserts that Claims 1 and 2 are incomplete because they recite a method for immunizing, but fail to state that expression of the claimed epitopes would in fact produce immunization. The Examiner suggests that this rejection would be obviated if Claims 1 and 2 were amended so that the final step indicated that the infant mammal was immunized by the claimed method. Applicants hereinabove have amended Claims 1 and 2 to indicate that the claimed method results in immunization of the infant mammal. In light of these amendments,

Applicants respectfully request withdrawal of the rejection of Claims 1-2 under the second paragraph of 35 U.S.C. § 112.

IV. The Claims are Not Anticipated

Claims 1-3 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bot *et al.* (*Viral Immunology* 1996;9(4):207-210), by Lai *et al.* (*Hepatology* 1993;18:763-767), by Assateerawatt *et al.* (*Asian Pacific Journal of Allergy and Immunology* 1993;11:85-91), and/or by del Canho *et al.* (*J. Medical Virol.* 1993;41:30-34).

Claims 1-3 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bot *et al.* According to the Examiner, Bot *et al.* teach the immunization of infant mice using a recombinant nucleic acid encoding the influenza NP peptide, and concludes that these teachings anticipate the disclosure in the instant specification of the method of immunizing an infant mammal using a recombinant nucleic acid molecule. Applicants respectfully remind the Examiner that the instant application is a continuation-in-part of U.S. Patent Application Serial Number 09/308,511 of Bot *et al.*, filed May 19, 1999, which was a national stage application of International PCT application PCT/US97/21687, filed on November 21, 1997, which in turn claimed priority to U.S. application Ser. No. 08/755,034, now U.S. Patent 6,204,250, filed November 22, 1996. Although, as a CIP application, some matter has been added to the instant application relative to its parent (*e.g.* several examples detailing specific embodiments of the invention), Applicants submit that Claims 1-3 are fully supported by the disclosure of U.S. application Ser. No. 08/755,034 as filed on November 22, 1996 and thus are entitled to this effective filing date. The cited reference of Bot *et al.* was published in *Viral Immunology* in December of 1996, and therefore does not constitute prior art against Claims

1-3 of the instant application. Applicants respectfully request that the Examiner withdraw the rejection of Claims 1-3 under 35 U.S.C. § 102(b) as being anticipated by Bot *et al.*

Claims 1-3 are rejected under 35 U.S.C. § 102(b) as being anticipated by the teachings of Lai *et al.* (*Hepatology* 1993;18:763-767), Assateerawatt *et al.* (*Asian Pacific Journal of Allergy and Immunology* 1993;11:85-91), or del Canho *et al.* (*J. Medical Virol.* 1993;41:30-34). According to the Examiner, each of these references teaches a method of immunizing neonates against hepatitis B via injection of DNA encoding a hepatitis B antigen.

Although admittedly this point is not abundantly clear upon a cursory reading of the cited references, Applicants assert that each of these references discloses immunizations involving the inoculation of infants with hepatitis B protein antigens, *i.e.* immunization with peptides, not with recombinant nucleic acid molecules, *i.e.* DNA. In support of this assertion, Applicants direct the Examiners attention to p. 20, lines 1-4 of the "Protocol" section of Lai *et al.*, 1986, p. 763, lines 1-6 of the "Protocol" section of Lai *et al.*, 1993, p. 86, lines 1-4 of the "Hepatitis B vaccine and HBIG" section of Assateerawatt *et al.*, 1993, and to p. 31, lines 1-5 of the "Vaccine and Vaccination-Schemes" section of del Canho *et al.*, 1993, wherein the identity of the vaccines employed in these studies are disclosed. Lai *et al.* use the Merck H-B-VAX II vaccine. Assateerawatt *et al.* use the Pasteur Vaccins GenHevac B Pasteur vaccine. del Canho *et al.* use the SmithKline Beecham Engerix-B vaccine.

Each of these vaccines is comprised of purified hepatitis B antigens. The phrase "recombinant DNA" is employed merely to indicate that the source of the various hepatitis B antigens was recombinant hepatitis B DNA that was introduced into a host organism such as yeast or cultured mammalian cells, where the hepatitis B antigens were then expressed and from which the protein antigens were purified prior to their incorporation into the vaccines.

The Examiner's attention is further directed to Exhibits A and B, attached hereto. Exhibit A indicates that the H-B-VAX II vaccine used by Lai *et al.*, also known as RECOMBIVAX HB, is a vaccine derived from hepatitis B surface antigen produced in yeast. Exhibit B indicates that Engerix-B, the vaccine used by del Canho *et al.*, is derived from purified hepatitis B surface antigen produced by yeast. Additionally, in Assateerawatt *et al.*, p. 86, lines 1-7 of the first column, it clearly states that the vaccine utilized for the immunization studies "...contain[ed] pre S1, pre S2 and S proteins produced in mammalian cells." Thus, each of the cited references fail to disclose immunizations carried out with nucleic acid molecules rather than peptide antigens. Therefore, the cited references cannot anticipate the claims of the instant invention, as presently amended, and the rejection under 35 U.S.C. § 102 (b) should be withdrawn.

CONCLUSION

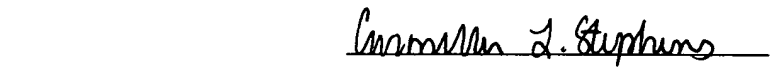
Based on the foregoing remarks and in light of the amendments, Applicants submit that the present application is in condition for allowance. A Notice of Allowance is therefore respectfully requested.

Applicants believe a fee of $530.00 is due with this response, representing the $475.00 fee required under 37 C.F.R. § 1.17(a)(3) for a three-month extension for a small entity and the $55.00 fee required under 37 C.F.R. § 1.20(d) for processing a Terminal Disclaimer for a small entity. A check in that amount is enclosed. Should any additional fees be required in connection with this filing, the Commissioner is hereby authorized to charge Deposit Account Number 02-4377. Two copies of this communication are enclosed.

If a telephone interview would be of assistance in advancing the prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone at the number provided below.

Respectfully submitted,

BAKER BOTTS L.L.P.



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